Gemore Technology Co., Ltd.

AUG 2 5 2011

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K102926

1. Submitter's Identifications:
   Gemore Technology Co., Ltd.
   11FL., NO. 29-5, Sec. 2, Chung Cheng E. RD.,
   Tan Shui, Taipei Hsien, Taiwan

   Contact:
   Mr.Boden S.P. Lai
   President & Official Correspondent

   Date of Summary Preparation: September 25, 2010.

2. Name of the Device:

Trade name:	Gemore Muscle Conditioner; models GM310PE/ GM320PE/ GM330PE/GM340PE/GM350PE
Common name:	Powered Muscle Stimulator
Classification name:	Stimulator, Muscle, Powered
Product Code:	NGX

3. Information of the 510(k) Cleared Device (Predicate Device):

   For this 510(k) submission, we compared our models to the following FDA cleared OTC devices:
   - K091833: GEM-TONE Abdominal Training System, model **GEM-TONE 310PE/ 320PE/330PE/ 340PE/350PE.**
   - K071666: Slendertone EnerVive™ Type 561.

4. Device Description:

   The Gemore Muscle Conditioner, model GM310PE/GM320PE/GM330PE/GM340PE/GM350PE are the battery-operated programmable muscle stimulator intended to improve or facilitate muscle performance by applying an electrical current to electrodes, which is attached on the healthy muscle.

   Gemore Muscle Conditioner, model GM310PE/GM320PE/GM330PE/GM40PE/GM350PE, consists mainly of three parts: the stimulator , special butterfly type self-adhesive electrode (GelPads), and leader wire fitting for the stimulation of any healthy muscle of body. The stimulator generates the output current specified as the input of controller. The output port transmits the output current to the electrode, which is attached to the specified region, so as to transmit this stimulus current to the healthy muscle the following intended purposes:
   - to stimulate healthy muscles in order to improve or facilitate muscle performance.

The Gemore Muscle Conditioner and its stimulation programs are not designed for injured or ailing muscles, and use on such muscles is contraindication.

5. Intended Use:

Basically the indication for use is defined clearly as the description of the following statement:

The Gemore Muscle Conditioner, model GM310PE/GM320PE/GM330PE/GM340PE/ GM350PE are intended to stimulate healthy muscles in order to improve or facilitate muscle performance.

The Gemore Muscle Conditioner, model GM310PE/GM320PE/GM330PE/GM340PE/ GM350PE are not intended to be used in conjuction with therapy or treatment of medical diseases or medical conditions of any kind. None of the Gemore Muscle Conditioned training programs are designed for injured or ailing muscle and it's use on such muscle in contraindicated.

The Gemore Muscle Conditioner, model GM310PE/GM320PE/GM330PE/GM340PE/ GM350PE electrically impulse triggering actions potentials on motoneurones of motor nerves(excitations). The excitations of motoneurones are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber response that correspond to muscle work. Depending on the parameters of the electrical impulses(pulse frequency, duration of contraction, duration of rest, total session duration), different type of muscle work can be imposed on the stimulated muscles.

The various types of muscle work that Gemore Muscle Conditioner can impose on the stimulated muscles are able to improve or facilitate muscle performance. The Gemore Muscle Conditioner, model GM310PE/GM320PE/GM330PE/GM340PE/ GM350PE may therefore be considered a technique of muscle training.

6. Discussion of Non-Clinical Tests Performed Determination of Substantial Equivalence are as follows:
Compliance to applicable voluntary standards includes ANSI/AAMI, NS4-1985, as well as EN 60601-1, EN 60601-1-1, and EN 60601-1-2 requirement. In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA software guidance.

7. Conclusions

The Gemore Muscle Conditioner, model GM310PE/GM320PE/GM330PE/GM340PE/ GM350PE have the same technological characteristics as the of the 510(K) cleared device, the GEM-TONE Abdominal Training System, model GEM-TONE 310PE / 320PE /330PE /340PE /350PE(K091833), and have the same intended use as the cleared device of Slendertone EnerVive™ Type 561(K071666) . Moreover, verification and validation tests contained in this submission demonstrate that the difference in the submitted demonstrate that the difference in the submitted model could maintain the same safety and effectiveness as that of cleared device.

In the other words, those engineering difference do not: (1) affect the intended use or (2) alter the fundamental scientific technology of the device. Therefore, the Gemore Muscle Conditioner, model GM310PE/GM320PE/GM330PE/GM340PE/ GM350PE are substantial equivalent to the chosen predicate model.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Gemore Technology Co., Ltd.
% Mr. Boden S.P. Lai
11 Fl., NO. 29-5, Sec. 2, Chung Cheng E. Road
Tan Shui, Taipei Hsien
Taiwan

AUG 25 2011

Re: K102926
Trade/Device Name: Gemore Muscle Conditioner, model GM310PE/GM320PE/GM330PE/GM340PE/GM350PE
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: NGX
Dated: August 3, 2011
Received: August 5, 2011

Dear Mr. Lai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K102926

Device Name: Gemore Muscle Conditioner, model GM310PE/GM320PE/ GM330PE/GM340PE/ GM350PE

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The various types of muscle work that Gemore Muscle Conditioner can impose on the stimulated muscles are able to improve or facilitate muscle performance. The Gemore Muscle Conditioner, model GM310PE/GM320PE/GM330PE/GM340PE/ GM350PE may therefore be considered a technique of muscle training.

Prescription Use _____ OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102926